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MAY 2 2 2014

K141220

Special 510(k) Summary
Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with SDS Software

Submitter: Thermo Fisher Scientific
Life Sciences Solutions Group
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Singapore 739256

Manufacturer: Life Technologies Holdings Pte Ltd
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Date Prepared: May 22, 2014

Device Information:

Proprietary Trade Name: Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with SDS Software

Common Name: 7500 Fast Dx

Device Class: Class II

Classification Name: Instrumentation for Clinical Multiplex Test Systems (21 CFR 862.2570)

Product Code: NSU

Predicate Device: K082562, Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with SDS Software version 1.4

Device Description: The Applied Biosystems® 7500 Fast Dx Real-Time PCR instrument integrates a thermal cycler, a fluorimeter and application specific software. The instrument houses the thermal cycler and the fluorimeter, while the application software is run on a PC that is attached to the instrument. Samples are placed in a tube strip or 96-well low-head space plate that is moved to a Peltier-based thermal block and positioned relative to the optics using a tray loading mechanism.

Excitation for all samples is provided by a halogen tungsten white source that passes

through 5 switchable excitation filters prior to reaching the sample. Fluorescence emission is then detected through 5 color emissions filter wheel to a charge coupled device (CCD) camera. The instrument is designed to complete quantitative RT-PCR runs in about 40 minutes.

The Sequence Detection Software (SDS) is used for instrument control, data collection and data analysis. The software provides a wizard for user-friendly set-up. The software measures cycle-by-cycle real-time signals from the sample and provides a variety of tools to help the user analyze the data extracted from the samples. In addition, the software provides lamp-life monitoring and other instrument maintenance information. The software runs as an application on the Windows 7 platform.

Intended Use/Indications of Use: The Applied Biosystems® 7500 Fast Dx Real-Time PCR instrument with the SDS Software is a real-time nucleic acid amplification and five color fluorescence detection system for use with FDA cleared or approved tests on human-derived specimens. The 7500 Fast Dx Real-Time PCR instrument and SDS Software are intended for use in combination with in vitro diagnostic tests labeled for use on this instrument. The 7500 Fast Dx instrument is intended for use by laboratory professionals trained in laboratory techniques, procedures, and on use of the system.

Minor changes were made to the intended use in order to remove the specific software version, to modernize, and to implement consistency. The changes are not substantive changes in the use of the device and do not affect the safety and effectiveness of the device when used as labeled.

Summary of technological characteristics of the device compared to the predicate device:

The Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with SDS Software is substantially equivalent to the predicate device Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with SDS Software version 1.4 (K082562). A comparison table is provided below:

Table 1: Predicate Comparison Table

Item	**Subject Device:** Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with SDS Software	**Predicate Device:** Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with SDS Software version 1.4
Indications for Use	The Applied Biosystems 7500 Fast Dx Real-Time PCR instrument with the SDS Software is a real-time nucleic acid amplification and five color fluorescence detection system for use with FDA cleared or approved tests on human-derived specimens. The 7500 Fast Dx Real-Time PCR instrument and SDS Software are intended for use	Applied Biosystems® 7500 Fast Dx Real-Time PCR instrument with the SDS Software version 1.4 is a real-time nucleic acid amplification and detection system that measures nucleic acid signals from reverse transcribed RNA and converts them to comparative quantitative readouts using fluorescent detection of dual-labeled

	in combination with in vitro diagnostic tests labeled for use on this instrument. The 7500 Fast Dx instrument is intended for use by laboratory professionals trained in laboratory techniques, procedures, and on use of the system.	hydrolysis probes. The 7500 Fast Dx instrument is to be used only by technologists trained in laboratory techniques, procedures, and on use of the analyzer.
Fundamental Technology	Real-Time PCR	Same
Instrument Computer Operating System	Windows 7	Windows XP

Non-clinical Testing Performed for Determination of Substantial Equivalence: Based on the risk analysis evaluation results, verification testing was conducted to support the modifications in the instrument computer operating system. The verification testing report included in the submission supports substantial equivalence to the predicate device.

Conclusion: The Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with SDS Software has the same operating principle and technological characteristics as the previously cleared device. The changes in intended use were made only to remove the software version and to modernize the language; there is no change in the use of the device. In summary, the Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with SDS Software is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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May 22, 2014

Re: K141220
Trade/Device Name: Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with SDS Software
Regulation Number: 21 CFR 862.2570
Regulation Name: Instrumentation for clinical multiplex test systems
Regulatory Class: II
Product Code: NSU
Dated: May 13, 2014
Received: May 14, 2014

Dear Ms. Arora:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

John Hobson -S for

Sally Hojvat, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141220

Device Name
Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with SDS Software

Indications for Use *(Describe)*
The Applied Biosystems 7500 Fast Dx Real-Time PCR instrument with the SDS Software is a real-time nucleic acid amplification and five color fluorescence detection system for use with FDA cleared or approved tests on human-derived specimens. The 7500 Fast Dx Real-Time PCR instrument and SDS Software are intended for use in combination with in vitro diagnostic tests labeled for use on this instrument. The 7500 Fast Dx instrument is intended for use by laboratory professionals trained in laboratory techniques, procedures, and on use of the system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

John Hobson -S
2014.05.22 12:33:44 -04'00'